**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MINNESOTA**

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| In re: MIRAPEX PRODUCTS LIABILITY LITIGATION | MDL No. 07-1836 (JMR/FLN) |
| This document relates to: | |
| JOHN BURBRIDGE<br>MELINDA BRAKEN-HOF, *et al.*<br>RONALD GERARD<br>JOAN MAILE | Civil No. 07-cv-3654-JMR-FLN<br>Civil No. 07-cv-3655-JMR-FLN<br>Civil No. 07-cv-3656-JMR-FLN<br>Civil No. 07-cv-3651-JMR-FLN |
| Plaintiffs,<br><br>v.<br><br>BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; PFIZER INC.; PHARMACIA CORPORATION; PHARMACIA & UPJOHN COMPANY LLC,<br><br>Defendants. | **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM (FED. R. CIV. P. 12 (b)(6))** |

## I. INTRODUCTION

Plaintiffs have failed to state claims for (1) Misrepresentation and Concealment, (2) Fraud and Deceit – Fraudulent Concealment, and (3) Negligent Misrepresentation because their complaint does not allege fraud with the particularity required by Federal Rule of Civil Procedure 9(b). Plaintiffs' fraud allegations amount to a mere speculative suggestion that defendants knowingly and intentionally sought to deceive plaintiffs, physicians, and the public at large about a purported connection between Mirapex and compulsive behavior. Under Rule 9(b), these conclusory allegations are inadequate, and plaintiffs' failure to plead the circumstances constituting the alleged fraud with any semblance of particularity is grounds to dismiss their claim under Rule 12(b)(6).

## II. BACKGROUND

Plaintiffs filed a complaint seeking to recover for injuries they claim were caused by ingestion of Mirapex. The causes of action asserted in the complaint fall into four categories of claims: claims sounding in strict products liability, claims sounding in negligence, claims sounding in breach of warranty, and claims sounding in fraud. Each of these claims is based on plaintiffs' allegation that Mirapex caused plaintiffs to develop compulsive gambling. (Complaint at ¶8).

Plaintiffs' fraud-based claims for "Misrepresentation and Concealment," "Fraud and Deceit – Fraudulent Concealment," and "Negligent Misrepresentation" are the focus of this Motion to Dismiss. (Complaint ¶¶58-66 or 61-69 (misrepresentation and concealment) and 67-76 or 70-79 (fraud and deceit – fraudulent concealment) and 83-90 or 86-93 (negligent misrepresentation)).[1] These fraud claims assert that defendants made misrepresentations to and/or concealed information from "prescribing physicians, hospitals, clinics, and other health care providers, and consumers, including Plaintiff" relating to the safety and use of Mirapex and the alleged risk of compulsive behavior. (Complaint at, *e.g.*, ¶¶61 or 64, 68 or 71, 84 or 87). Plaintiffs claim that these statements and/or concealments may have included failures to disclose information about the safety of Mirapex, including the sufficiency of pre-clinical, clinical, and/or post-marketing surveillance, results of animal and/or human tests, potential and actual risks and/or other information about serious side effects, and the "known and true risks of compulsive

[1] Plaintiffs' complaints are substantially the same. Therefore this motion applies equally to each of the complaints listed in the caption. However, where a claim for plaintiff spouse is included in a complaint, the numbering of the paragraphs of fraud allegations shift. To account for this difference in paragraph numbering, defendants cite to alternate paragraph numbers for fraud allegations in this brief. Otherwise the pleadings are virtually identical.

behavior." (Complaint ¶¶61(a)-(d) or 64(a)-(d), 84 or 87, 68 or 71). Plaintiffs allege that these fraudulent statements and/or concealments were effected through a variety of media, including "advertising and promotional campaigns and materials, in standardized packaging inserts, in correspondence to health care professionals, in submissions and reports to the FDA, among other ways[.]" (Complaint ¶60 or 63). These allegations lack the requisite specificity as to who was involved, and when or where the alleged misrepresentations or concealment occurred.

## III. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), the Court should grant a motion to dismiss when "it is clear that no relief can be granted under any set of facts that could be proved consistent with the allegations" in the complaint. *Alexander v. Peffer*, 993 F. 2d 1348, 1349 (8th Cir. 1993). However, a complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level[,] ... [and must contain] "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombley*, 127 S. Ct. 1955, 1965, 1974 (2007) (overruling *Conley v. Gibson*, 355 U.S. 41 (1957)). In evaluating a motion to dismiss, the Court is "free to ignore legal conclusions, unsupported conclusions, unwarranted inferences, and sweeping legal conclusions cast in the form of factual allegations." *Farm Credit Servs. Of Am. v. Am. State Bank,* 339 F. 3d 764, 767 (8th Cir. 2003).

## IV. LEGAL ARGUMENT

### A. Federal Rules Require Claims Sounding In Fraud To Be Pled With Specificity

Under Federal Rule of Civil Procedure 9(b), claims for fraud must be pled with particularity, even where, as here, state law supplies the underlying substantive law. Fed.

R. Civ. P., R. 9(b). Intentional misrepresentation, negligent misrepresentation, and concealment all sound in fraud and, therefore, are included within the ambit of Rule 9(b)'s heightened pleading requirements. *See, e.g., Evans v. Rudy-Luther Toyota, Inc*., 39 F. Supp. 2d 1177, 1185 n.5 (D. Minn. 1999) (holding that plaintiffs seeking to invoke doctrine of fraudulent concealment must comply with Rule 9(b)); *Conwed Corp. v. Employers Reinsurance Corp.*, 816 F. Supp. 1360, 1363 (D. Minn. 1993) ("negligent misrepresentation claims sound in fraud and must satisfy the Rule 9(b) particularity requirement.").

Rule 9(b)'s particularity requirements are designed to enable defendants to respond specifically, at an early stage of the case, to inflammatory and potentially damaging allegations. *BJC Health System v. Columbia Cas. Co.*, 478 F.3d 908, 917 (8th Cir. 2007); *United States v. Napco Int'l*, 835 F. Supp. 493, 495 (D. Minn. 1993). Rule 9(b) also specifically seeks to "to inhibit the filing of a complaint as a pretext for discovery of unknown wrongs" and to "protect defendants from the harm that results from charges of serious wrongdoing." *United States v. Napco Int'l.*, 835 F. Supp. at 495. Thus, "[c]onclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." *Id.* (quoting *Commercial Property Investments Inc. v. Quality Inns Int'l Inc.*, 61 F.3d 639, 644 (8th Cir. 1995)).

To protect these interests and provide proper notice, federal courts typically require plaintiffs to identify the "who, what, where, when, and how" of the alleged fraud. *BJC Health System*, 478 F.3d at 917. This includes pleading specific facts that give notice of "such matters as the ***time***, ***place*** and ***contents*** of false representations, as well as the ***identity of the person*** making the misrepresentation and ***what*** was obtained or given up thereby." *Id.* (emphasis added); *accord, Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920 (8th Cir. 2001); *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 549-50 (8th

Cir. 1997); *Kranz v. Koenig*, 240 F.R.D. 453, 454-55 (D. Minn. 2007). Likewise, a plaintiff must plead the particulars of fraudulent concealment – what was concealed, who concealed it, when it was concealed and how it was concealed. *See Evans v. Rudy-Luther Toyota, Inc.*, 39 F. Supp. 2d 1177, 1185 (D. Minn. 1999) (holding that plaintiff "failed to plead the circumstances, which are purported to constitute fraudulent concealment, with the particularity that is required by Rule 9(b)[.]"); *Great Plains Trust Co. v. Union Pacific Railroad Co*., Civ. No. 06-3440, 2007 U.S. App. LEXIS 15489, *18 (8th Cir. June 29, 2007) (pleading concealment claims "with particularity means the who, what, when, where, and how: the first paragraph of any newspaper story."). Accordingly, conclusory allegations that fail to "state when or how [defendant] perpetrated its alleged concealment" are insufficient to state a claim for fraudulent concealment under Rule 9(b)'s heightened pleading requirements. *See id.* at *19.

In these cases, as in all others alleging fraud, "[p]laintiffs must accompany their legal theory with factual allegations that make their theoretically viable claim plausible." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997) (plaintiff failed to state claim for securities fraud with particularity required by Rule 9(b)); *In re TMJ Implants Prods. Liab. Litig.*, 872 F. Supp. 1019, 1038 (D. Minn. 1995) (dismissing fraudulent concealment claims that lacked particularized factual allegations); *Great Plains Trust Co*, 2007 U.S. App. LEXIS 15489 at *18 ("conclusory allegation--that Union Pacific fraudulently concealed its correct ANI for 1998--also fail[ed] to allege how or when this concealment occurred."). Thus, even where factual information is peculiarly within the defendant's knowledge and control, "boilerplate and conclusory allegations will not suffice." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1418. So too, even where fraud allegations are based explicitly or implicitly on information and belief, "the complaint [still] must set forth the source of the information and the reasons for the belief." *Parnes v. Gateway 2000*, 122 F.3d 539, 550 (8th Cir. 1997).

Conclusory allegations that defendants concealed material information or made fraudulent statements which caused injury do not meet Rule 9(b)'s exacting standard. *Tuttle v. Lorillard Tobacco Co.*, 118 F. Supp. 2d 954 (D. Minn. 2000). The *Tuttle* complaint alleged that defendants fraudulently misrepresented that the product at issue was safe, pleading:

> Defendants' wrongful conduct includes . . . fraudulent, misleading, and deceptive statements and practices relating to the use of smokeless tobacco and health, including fraudulent representations that there is no causal connection between the use of smokeless tobacco and adverse health effects.

*Id.* at 964. The district court granted defendants' motion to dismiss, holding that the *Tuttle* complaint's allegations failed to apprise the defendants of the claims against them and the acts relied upon as constituting the fraudulent conduct. *Id.*; *Russo v. NCS Pearson, Inc.*, 462 F. Supp. 2d 981, 1003 (D. Minn. 2006) (dismissing a fraud claim where plaintiffs relied on sweeping allegations and failed to plead the who, what, where, when and how of their claim).

### B. Plaintiffs' "Misrepresentation and Concealment," "Fraud and Deceit" and "Negligent Misrepresentation" Claims Should Be Dismissed for Failure to Allege the Circumstances Constituting Fraud with Particularity

Here, plaintiffs' allegations in support of their claims for misrepresentation and concealment do not meet the particularity requirements of Rule 9(b). To begin with, plaintiffs do not allege who made the purported misrepresentations or to whom they were communicated. They do not identify who among "defendants" was responsible for the alleged misrepresentations or concealments, and they likewise do not allege the identity of the physicians or any other person to whom any alleged misrepresentations were made. Their generic, boilerplate allegations that a misrepresentation was made to or information concealed from "prescribing physicians, hospitals, clinics and other health care providers,

and consumers, including Plaintiff . . . the general public . . . and/or treating physicians" do not include the required specificity. (Complaint ¶61 or 64, 68 or 71, 84 or 87)

Plaintiffs similarly do not allege when the purported misrepresentations were made, where they were made, or in what manner. They allege that defendants made misrepresentations and/or concealed information in "advertising and promotional campaigns and materials, in standardized package inserts, in correspondence to health care professionals, in submissions and reports to the FDA, among other ways . . . ." or that the "representations were made directly by defendants to plaintiff, by sales representatives and other authorized agents of said defendants and in publications, and literature regarding the product, the product inserts, product labels, and other written materials regarding the product."[2] (Complaint ¶60 or 63, 74 or 77) But these all-encompassing allegations again fail to provide defendants with the requisite notice of the specific communication which is alleged to have contained misrepresentations or concealed information. *See Bennett v. Berg*, 685 F.2d 1053 (8th Cir. 1982) (allegations that "false statements [were] said to be in a 'pamphlet,' 'promotional material,' or 'a typical life-care contract' . . . are not sufficiently particular to satisfy Rule 9(b).").

Likewise, plaintiffs do not allege that they saw, read, heard, or were otherwise aware of any specific statement, nor do they aver that plaintiff's physician(s) saw, read, heard, or were otherwise aware of any such statement. This alone defeats plaintiffs' misrepresentation and fraud claims, as it is impossible for a person to rely to her detriment on a statement that she never received. It is similarly impossible for a prescribing physician to be influenced by statements of which he or she was never aware.

[2] Plaintiffs include no allegations concerning the nature of the alleged misrepresentation anywhere in their Negligent Misrepresentation count.

*See In re NationsMart Corp. Sec. Litig.*, 130 F.3d 309, 322 (8th Cir. 1997) (plaintiffs did not adequately plead actual reliance under Rule 9(b), where they did not claim that they ever read the stock prospectus in question or specify which allegedly fraudulent statements they relied on in purchasing defendant's stock).

Indeed, were one to substitute another alleged injury for the "compulsive behavior" attributed to the unnamed drug in this complaint, this generalized boilerplate allegation could easily be cut and pasted into a complaint for injuries involving any other pharmaceutical product:

> Defendants . . . misrepresented to, and suppressed and/or concealed material facts from, prescribing physicians, hospitals, clinics, and other health care providers, and consumers, including Plaintiff, that the Product was safe when used as intended for signs and symptoms of Parkinson's Disease and/or Restless Leg Syndrome. Those misrepresentations and concealments and suppression of facts concerning the Product included, without limitation: (a) Failing to disclose that sufficient pre-clinical and clinical testing and adequate post-marketing surveillance had not been done; (b) Failing to adequately and timely disclose, and/or intentionally concealing, the results of animal and/or human tests showing the risk of potential risk of serious compulsive behavior associated with the use of the Product; (c) Failing to include adequate warnings with the Product about the potential and actual risks and the nature, scope, severity, and duration of any serious side effects of the Product, including without limitation, the risks of compulsive behavior; (d) Actively suppressing and/or downplaying the known and true risks of compulsive behavior.

(Complaint ¶61 or 64). Plaintiffs' claim for "Fraud and Deceit – Fraudulent Concealment" makes a similarly generic allegation:

> At all times during which defendants and each of them tested, produced, manufactured, sold, distributed, marketed, processed, supplied Mirapex, and up to the present, defendants and each of them, knowingly, intentionally, willfully, and purposefully deceived plaintiff by (1) making false and fraudulent misrepresentation to the plaintiff, his physician and the general public including, but not limited to, that said product was safe, fit,

> and effective for human consumption; and (2) concealing from the plaintiff, his physicians, and the general public the true facts known by defendants concerning the safety and efficacy of said product.

(Complaint ¶68 or 71). Plaintiffs' Negligent Misrepresentation claim is even less particularized:

> At all times during which the defendants . . . formulated, tested, produced, manufactured, sold, distributed, marketed, processed or supplied Mirapex, defendants falsely and negligently represented to plaintiff, the public and/or treating physicians, as consumers, patients and prescribing physicians that this product was safe for human consumption.

(Complaint ¶84 or 87). Even in coordinated proceedings, fraud allegations must be unique to the specific people, timeframe, and product involved in a case, not pre-fabricated paragraphs from a single mold that could apply to any pharmaceutical products liability case in the country.

Even where the complaint purports to identify defendants' alleged concealments, plaintiffs do so in a broad and generic way that fails to point the Court or defendants to any specific act. In doing so, plaintiffs fail to state the source of the information or the basis for their belief that defendants fraudulently concealed material facts about the safe use of Mirapex. Although plaintiffs assert that defendants failed to disclose

> that sufficient pre-clinical and clinical testing and adequate post-marketing surveillance had been done; [failed to disclose] the results of animal and/or human tests showing the risk or potential risk of serious compulsive behavior; [failed to disclose] potential and actual risks . . . of any serious side effects[,] including . . . compulsive behavior; [and] [a]ctively suppress[ed] . . . the known and true risks of compulsive behavior,

(Complaint ¶ 64(a)-(d) or 61(a)-(d)), plaintiffs fail to identify the factual information supporting *their* belief that defendants had knowledge related to these categories of

information. *See, e.g. In re TMJ Implants Prods. Liab. Litig.*, 872 F. Supp. 1019, 1038 (D. Minn. 1995) (claim for fraudulent concealment dismissed where plaintiff failed to allege "any facts that could give rise to the inference that the . . . Defendants had knowledge of any material facts that they may have concealed from her regarding the safety of the" allegedly defective product).

In sum, plaintiffs are hazarding their fraud claims on speculation that there ***could have been*** fraud involved in some aspect of the information contained in myriad communications, in "advertising and promotional campaigns and materials, in standardized package inserts, in correspondence to health care professionals, in submissions and reports to the FDA, among other ways" of communicating. (Complaint ¶60 or 63). However, as in *Tuttle*, this is not enough to satisfy Rule 9(b) pleading standards, which are specifically geared toward deterring "the use of complaints as a pretext for fishing expeditions of unknown wrongs." *Parnes*, 122 F.3d at 549.

## V. CONCLUSION

Plaintiffs' generalized allegations of misrepresentation and concealment are boilerplate pleadings that do not meet Rule 9(b)'s standard. As a result, defendants respectfully request that the Court dismiss plaintiffs' causes of action for "Misrepresentation and Concealment," "Fraud and Deceit – Fraudulent Concealment," and "Negligent Misrepresentation."

DATED: August 30, 2007

FAEGRE & BENSON LLP

By s/ Steven J. Ellison
Joseph Price, #88201
Peter J. Goss, #267910
Steven J. Ellison, *#387538*
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-4501
(612) 766-8672

Michael K. Brown, Esq.
Barry J. Thompson, Esq.
Mildred Segura, Esq.
REED SMITH LLP
355 South Grand Avenue
Los Angeles, CA 90071

*Attorneys for Defendants Pfizer Inc., Pharmacia Corporation, and Pharmacia and Upjohn Company LLC*

HALLELAND LEWIS NILAN & JOHNSON, P.A.

By s/ Tracy J. VanSteenburgh
Tracy J. Van Steenburgh, #141173
U.S. Bank Plaza South, Suite 600
220 South Sixth Street
Minneapolis, Minnesota 55402-4501
(612) 338-1838

James E. Gray
Andrew Gendron
VENABLE LLP
Two Hopkins Plaza Suite 1800
Baltimore, MD 21201

Beth S. Rose, Esq.
Stuart M. Feinblatt, Esq.
Jennifer Ewers Hurley, Esq.
SILLS CUMMIS EPSTEIN & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102

*Attorneys for Defendant Boehringer Ingelheim Pharmaceuticals, Inc.*

fb.us.2265019.01